DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 5, 2014

BIOTRONIK, Inc.
Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, Oregon 97035

Re: K142379
Trade/Device Name: Passeo-35 Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: November 4, 2014
Received: November 5, 2014

Dear Mr. Brumbaugh,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142379

Device Name: Passeo-35 Peripheral Dilatation Catheter

Indications for Use:

The Passeo-35 Peripheral Dilatation Catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

BIOTRONIK
excellence for life

Passeo-35 Peripheral Dilatation Catheter Special 510(k) Premarket Notification

510(k) Summary

Name and Address of Sponsor:
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

510(k) Contact Person and Phone Number:
Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035
Phone: (888) 345-0374
Fax: (503) 635-9936
jon.brumbaugh@biotronik.com

Date Prepared: December 5, 2014

Device Name:

Proprietary Name:	Passeo-35 Peripheral Dilatation Catheter
Common Name:	Percutaneous Transluminal Angioplasty (PTA) Catheter
Classification:	Class II (21 CFR 870.1250)
Classification Name:	Catheter, angioplasty, peripheral, transluminal
Product Code:	LIT

Predicate Device:

	510(k) #	Device Name	Manufacturer	Date of Clearance
Predicate:	K082933	Passeo-35	BIOTRONIK	3-Nov-2008

General Description:

The Passeo-35 Peripheral Dilatation Catheter (Passeo-35) is intended for dilatation of stenotic segments in peripheral vessels. One radiopaque marker is located at either end of the balloon to facilitate fluoroscopic visualization and positioning of the balloon catheter towards and across the lesion. The dilatation balloon is designed to inflate to a known diameter at a specific inflation pressure consistent with the compliance chart on the label. The balloon catheter includes a tapered soft tip to facilitate advancement of the catheter.

The balloon catheter shaft has two Luer ports at the proximal end. One port (inflation port) serves for connecting an inflation device to inflate/deflate the balloon. The other port (guidewire port) enables insertion of the guide wire. The balloon catheter is a dual lumen design with both lumens contained within one tube. The smaller lumen is the balloon inflation/deflation lumen. The larger lumen permits the use of guide wires with a maximum diameter of 0.035” to facilitate advancement of the Passeo-35 catheter towards and through the lesion(s) to be dilated. The balloon catheter is compatible with introducer sheath (introducer) sizes according to the recommendations on the label. The balloon catheter has a silicone coating (hydrophobic) to improve the trackability and pushability characteristics.

BIOTRONIK
excellence for life

Indication for Use:

The Passeo-35 Peripheral Dilatation Catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Purpose of Submission:

BIOTRONIK submits this 510(k) for clearance of additional device size configurations for the Passeo-35 including additional balloon lengths up to 200mm. In addition, device and packaging materials changes are documented and labeling is updated for clarity as well as to reflect the new sizes and RBPs.

Technological Comparison to Predicate Device:

Substantial Equivalence of Passeo-35 to existing (predicate) Passeo-35 product line			
Parameters	**Passeo-35 K082933**	**Passeo-35 Subject Device**	**Rationale for Substantial Equivalence**
Proprietary name	Passeo-35 Peripheral Dilatation Catheter	Passeo-35 Peripheral Dilatation Catheter	Same
Common name	PTA catheter	PTA catheter	Same
Classification	Class II (21 CFR 870.1250)	Class II (21 CFR 870.1250)	Same
Classification name	Catheter, angioplasty, peripheral, transluminal	Catheter, angioplasty, peripheral, transluminal	Same
Product code	LIT	LIT	Same
Intended use / Indications for Use			
Intended use	The Passeo-35 Peripheral Dilatation Catheter is intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae.	The Passeo-35 Peripheral Dilatation Catheter is intended for dilatation of stenotic segments in peripheral vessels and arteriovenous dialysis fistulae.	Same
Indications for Use	The Passeo-35 Peripheral Dilatation Catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	The Passeo-35 Peripheral Dilatation Catheter is indicated to dilate stenosis in the renal, iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.	Same

BIOTRONIK
excellence for life

Substantial Equivalence of Passeo-35 to existing (predicate) Passeo-35 product line			
Parameters	**Passeo-35 K082933**	**Passeo-35 Subject Device**	**Rationale for Substantial Equivalence**
Contraindications	All general contraindications for percutaneous transluminal angioplasty (PTA) are contraindications for this device. Contraindications for this device and peripheral dilatation catheters in general are: • Lesions that cannot be reached or treated with the system • Large amounts of acute or subacute thrombus at the target lesion • Perforated vessels • Lesion that lies within or adjacent to an aneurysm • Uncorrected bleeding disorders • Renal insufficiency or an allergy to contrast media Furthermore, all procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply.	All general contraindications for percutaneous transluminal angioplasty (PTA) are contraindications for this device. Contraindications for this device and peripheral dilatation catheters in general are: • Lesions that cannot be reached or treated with the system • Large amounts of acute or subacute thrombus at the target lesion • Perforated vessels • Lesion that lies within or adjacent to an aneurysm • Uncorrected bleeding disorders • Renal insufficiency or an allergy to contrast media Furthermore, all procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply.	Same
Intended user	Physicians competent in PTA procedures	Physicians competent in PTA procedures	Same
Method of placement	Standard percutaneous access to site over a guide wire, with fluoroscopic visualization	Standard percutaneous access to site over a guide wire, with fluoroscopic visualization	Same
Sterilization / Shelf life / Packaging			
Sterilization	EO gas	EO gas	Same
Sterilization System	Sauter EO Sterilizer	Sauter EO Sterilizer or Sterichem EO Sterilizer	Does not alter intended use. Validation testing according to design controls support equivalence. BIOTRONIK uses either sterilizer in production.
SAL	10^{-6}	10^{-6}	Same
Shelf life	3 years	3 years	Same

BIOTRONIK
excellence for life

Substantial Equivalence of Passeo-35 to existing (predicate) Passeo-35 product line			
Parameters	**Passeo-35 K082933**	**Passeo-35 Subject Device**	**Rationale for Substantial Equivalence**
Protective sheath	Balloon has a protective sheath. Spiral dispenser sealed in a Tyvek® and PET/PE pouch. Product is packed in an outer cardboard carton.	Balloon has a protective sheath. Spiral dispenser sealed in a Tyvek® and PET/PE pouch. Product is packaged in an outer cardboard carton.	Same
Shelf life	3 years	3 years	Same
Instructions for Use and labeling	As provided in K082933.	Minor wording & symbol changes	Changes do not alter intended use, technological characteristics, or raise different questions of safety and effectiveness.
Device Design			
Device description	Over the wire 2-lumen balloon catheter	Over the wire 2-lumen balloon catheter	Same
Radiopaque markers	2 – one at each end of the balloon Material: 90% Pt / 10% Ir Length: 1.5 mm	2 – one at each end of the balloon Material: 90% Pt / 10% Ir Length: 1.5 mm	Same
Usable length [cm]	80 and 130	80, 90 and 130	Does not alter intended use. Performance testing according to design controls support equivalence.
Introducer sheath compatibility	5F (Balloon Ø: 3 – 7 mm) 6F (Balloon Ø: 8 – 10 mm)	5F (Balloon Ø: 3 – 7 mm) 6F (Balloon Ø: 8 – 10 mm)	Same
Crossing profile	Ø: 3–7mm: max. 0.074 inches Ø: 8–10mm: max. 0.083 inches	Ø: 3-7mm: max. 0.074 inches Ø: 8-10mm: max. 0.083 inches	Same
Guide wire compatibility	0.035”	0.035”	Same
Shaft outer diameter [F]	5	5	Same
Shaft inner diameter [mm]	0.96	0.98	The larger inner diameter of Passeo-35 LE does not alter the intended use or raise different safety and effectiveness questions. Performance testing data showed substantial equivalence to the predicate.
Balloon diameter [mm]	3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0	3.0, 4.0, 5.0, 6.0, 7.0, 8.0, 9.0, 10.0	Same

BIOTRONIK
excellence for life

Substantial Equivalence of Passeo-35 to existing (predicate) Passeo-35 product line			
Parameters	**Passeo-35 K082933**	**Passeo-35 Subject Device**	**Rationale for Substantial Equivalence**
Balloon length [mm]	20, 40, 60, 80, 100	20, 40, 60*, 80*, 100*, 120, 150, 170, 200 (* new balloon lengths for some balloon diameter sizes,)	Same intended use and does not raise different safety and effectiveness questions. Performance testing data demonstrate substantial equivalence.
Balloon wrapping	5 folds	5 folds	Same
Balloon Nominal pressure [atm]	7	7	Same
Balloon RBP [atm]	20 (Balloon Ø: 3 – 4 mm) 16 (Balloon Ø: 5 – 6 mm) 14 (Balloon Ø: 7 – 8 mm) 12 (Balloon Ø: 9 – 10 mm)	20 (Balloon Ø: 3mm) 18 (Balloon Ø: 4mm) 16 (Balloon Ø: 5 – 6 mm) 14 (Balloon Ø: 7 – 8 mm) 12 (Balloon Ø: 9mm) 11 (Balloon Ø: 10 mm)	Same intended use and does not raise different safety and effectiveness questions. Performance testing data demonstrate substantial equivalence.
Materials of Construction (Direct and indirect patient contact)			
Tip	Pebax 5533 SA01	Pebax 5533 SA01	Same
Balloon	Poly-Amide (PA)	Poly-Amide (PA)	Same
Catheter Shaft: Outer (2-lumen shaft) / Shaft extension tube: Inner shaft	Pebax 7033 SA01 Pebax 7233 SA01	Pebax 7033 SA01 Pebax 7233 SA01	Same
Hydrophobic coating (shaft and balloon)	Medical Grade Dispersion hydrophobic coating with heptane fraction	Medical Grade Dispersion hydrophobic coating with heptane fraction (new mixture ratio)	Same coating, different ratio of lubricant to heptane fraction. Biocompatibility supports change in coating.
Manifold (Luer hub)	Polycarbonate	Polycarbonate	Same
UV adhesive	Polyurethane Oligomer Mixture	Polyurethane Oligomer Mixture	Same
Materials of Construction (non-patient contacting)			
Radiopaque markers	2, Pt/Ir (90/10), length 1.5mm	2, Pt/Ir (90/10), length 1.5mm	Same
Kink protector	Pebax 5533 SA01	Pebax 5533 SA01	Same

Substantial Equivalence of Passeo-35 to existing (predicate) Passeo-35 product line			
Parameters	**Passeo-35 K082933**	**Passeo-35 Subject Device**	**Rationale for Substantial Equivalence**
Packaging Materials (non-patient contacting)			
Protective Sheath	Outer Layer Poly-Amide (PA) Middle Layer Linear Low Density Polyethylene, LDPE Inner Layer High density polyethylene, HDPE	Outer Layer Poly-Amide (PA) Middle Layer Maleic anhydride ethylene copolymer Inner Layer HDPE – new supplier	Material change for packaging does not alter safety and effectiveness of the device.
Dispenser (spiral ring and clips)	Ring: Polyethylene; Clips: Marlex and HDPE mix	Ring: Polyethylene; Clips: HDPE & LDPE mix	Materials and supplier change for packaging does not alter safety and effectiveness of the device.
Tyvek pouch	Material: PerfecFlex	Material: 20/50 OPA/PE peel film	Materials supplier and dimensional changes of packaging do not alter safety and effectiveness.

Biocompatibility Testing

Test Name	Test Description	Results
Cytotoxicity	L929 cells are incubated with test article extracts and evaluated for percentage of cell growth inhibition and compared to a control sample (control: cells exposed to extraction medium).	Growth analyses of cells cultured with test article extract showed no cytotoxic effects of the test article.
Sensitization	The test article is extracted polar/non-polar solution according to ISO 10993-12 and administered topically to mice for 3 days. After 5 days mice are sacrificed and lymph node cells are harvested and analysed to compute stimulation index (SI) vs. a negative sensitization control.	The stimulation index (SI), ratio of test article / negative control, was calculated for each concentration of the test article extract. No reactions were identified as sensitization
Irritation / Intracutaneous reactivity	The test article is extracted with 0.9 % Sodium chloride solution (polar) and Cottonseed Oil (non-polar) according to ISO 10993-12. Extracts are injected into rabbits and rabbits are observed for erythema and edema immediately after injection and after 24, 48, and 72 hours.	There were no signs of irritation of the polar and non-polar test article extracts injected intracutaneously into rabbits.

Test Name	Test Description	Results
Acute systemic toxicity	The test article is extracted with polar and non-polar extraction vehicles according to ISO 10993-12. Mice are injected with extracts and observed for adverse reactions immediately after dosing and again at 4, 24, 48, and 72 hours after injection. At termination mice were sacrificed and gross necropsy was carried out to record gross pathological changes.	There were no compound related mortalities, no significant body weight loss was recorded and all animals appeared clinically normal. At necropsy no evidence of gross pathology of organs was found. The test article was considered to have no acute toxic characteristics.
Pyrogenicity	The test article is extracted with sterile, non-pyrogenic polar solution according to ISO 10993-12. Extract is injected into rabbits and rectal body temperatures are measured and recorded prior to injection and up to 3 hours after injection.	No single animal showed a temperature increase higher or equal to 0.5°C above its initial temperature. The test article is considered to be non-pyrogenic.
Hemocompatibility	The test article is placed in a polymer tube filled with Heparin-anticoagulated whole human blood and rotated on a modified chandler-unit. The effects of the test article regarding TAT (thrombin-antithrombin complex), cell count and the hemolysis are evaluated by comparison to the predicate device.	There were no significant changes in the cell counts and the coagulation system activation value measured as TAT complex generation of the test article was identical in comparison with the reference. There was no evidence of hemolysis.
Gas Chromatography – Mass Spectrometry	The old materials are compared to the new materials. The test articles are extracted in different solvents (polar and non-polar, e.g. purified water, isopropyl alcohol and hexane) and the extracts are analyzed by GC-MS fingerprint analysis.	GC/MS fingerprint analysis of extractable semi-volatile organic compounds yielded no differences in the type of detected substances in the extracts. There are no significant differences between old and new materials
Fourier Transform Infrared Spectroscopy (FT-IR) analysis	Fourier Transform Infrared Spectroscopy (FT-IR) was utilized to compare the chemical composition of the new materials and old materials The resulting FT-IR spectra were compared.	Materials had greater than 99% correlation according to FT-IR analysis. The new materials are similar to the predicate.

Non-Clinical Performance Testing

Test Name	Test Conditions / Specifications	Summary Results
Visual and Dimensional Inspection	Test was performed according to ISO 25539-2:2008, ASTM F2081-06, DIN EN ISO 10555-1:1995 + AM1:1999 + AM2:2004, ISO 10555-4:1996/2002 + Cor1:2002 The balloon catheter was visually inspected as follows: a) visual check of catheter surface for defects. b) Correct printing on the device c) homogeneity of coating on the catheter d) Positioning of the X-ray markers e) usable length of the balloon catheter f) shaft inner diameter g) shaft outer diameter (prox/mid/dist) along different longitudinal paths (e.g., rotating test sample 90 degrees for measurements)	Inspectional acceptance criteria were met.
Crossing Profile (system profile)	This test was conducted as per ISO 25539-2:2008 and ASTM F2081-6. The diameter of the device is measured by passing the device through a ring-hole gauge. Crossing profile (proximal end of the balloon and the distal tip of the catheter) of the catheter evaluated in terms of smallest French size compatibility.	Acceptance criteria for crossing profile were met. Crossing profile is within specs of predicate.
Simulated Use Testing		
Simulated Use / Balloon Preparation, Deployment and Retraction	This test addresses the requirements for qualitative evaluation of simulated use, flex/kink, pushability, torquability and trackability of the system. The test is conducted by inserting, delivering and deploying the balloon in the model and then withdrawing the system while qualitatively evaluating pushability, torquability and trackability.	Acceptance criteria for balloon prep, deployment and retraction were met. Test shows device performs similar to predicate in a simulated use environment.
Deflated Balloon Profile	The friction to introduce and pullback after inflation was assessed. The test is conducted by measuring force required to insert and remove a deflated balloon as the device is passed through a ring-hole gauge.	Acceptance criteria were met: withdrawal force is less than minimal tensile and deflated balloon diameter is less than max crossing profile.
Trackability	All testing performed in a Crossover model. Trackability - recorded frictional force (N) over distance (mm) when tracked over a guide wire in arterial model and compared to predicates.	Acceptance criteria for comparison to the predicate were met.
Pushability	The test device is pushed through an anatomical model with a proximal force while the distal reaction force is measured. The pushing continues until a proximal force threshold is reached._The pushability force must be comparable or better (greater) than the existing Passeo-35 range.	Acceptance criteria for comparison to predicate devices were met.

Test Name	Test Conditions / Specifications	Summary Results
Torqueability / Torque Strength	The catheter is preconditioned with simulated use then the proximal end of the device is rotated counter clockwise until the first rotational movement at the distal end is observed. In this torqued position, the distal end of the device is clamped and the proximal end is rotated another 5 times and the device inflated and deflated to NP to verify that it can withstand the torsion.	Qualitative assessment showed rotation transfers to distal tip on average between 10 and 16 rotations and all balloons passed inflation test. Device meets torqueability and torque strength acceptance criteria.
Pullback and reintroduction test	The friction to introduce and pullback the device after inflation to RBP is measured. With the balloon in an appropriate sheath, the friction to introduce and pullback the device after inflation to RBP is evaluated. Introduction and pullback are repeated three times and on the third time, the balloon is intentionally burst before pullback to test if balloon can be pulled back safely in the event of a burst.	Pullback and reintroduction was comparable or better than comparator product. Product specifications were met for 1st and 2nd pullback force values. Balloon can be safely retrieved after burst.
Balloon Inflation / Deflation Time	Inflation and deflation times to RBP measured for characterization only. Inflation and deflation time are measured with the device placed in an anatomical model and a 50:50 mixture of contrast and saline are used to inflate to RBP. The inflation time from 0.5 bar to RBP is recorded. After holding the RBP for 30s, the plunger is pulled to create a vacuum while the time required for balloon to completely empty is recorded as deflation time.	Inflation time was characterized and deflation time was determined to be according to specifications within the instructions for use.
Flexibility and kink test	The catheter is advanced over a guidewire through a predefined curve, minimum radius of 20mm (clinically relevant radius) until the shaft is located in the corresponding radius. The guide wire movability is checked, and, subsequently, the balloon is inflated to NP and pressure is held for 30 s prior to deflation.	No kink occurred nor was the function of the device compromised at the clinically relevant radius of 20 mm. The guide wire was movable during testing and it was possible to inflate and to deflate the balloon to and from NP.
Particulate Evaluation	Particles were measured using the methods described in USP <788>. The process of balloon delivery, deployment and retraction is simulated using an in-vitro peripheral crossover model consisting of a specially designed tortuous path to represent the iliac arteries and the crossover radius at the abdominal aortic bifurcation. The number of sub-visible particulates is evaluated by an optical counter for solution samples collected after track, after retraction and cleaning. A statistical evaluation using the “t-test” analysis is conducted to compare the number of particulates measured of the Passeo-35 LE devices to predicate and marketed comparator devices.	The number of particulates released by the Passeo-35 LE were either the same as (p-value >0.05) or were less than the comparator device (p-value <0.05).

Test Name	Test Conditions / Specifications	Summary Results
X-ray Visibility (Visibility / Radiopacity)	Radiographic images are digitized and analysed quantitatively to determine the relative contrast with respect to reference aluminium plates with known thicknesses.	The markers are unchanged from the predicate and the predicate (K082933) results show that markers are visible with contrast values approximately equivalent to a 10mm thick aluminum plate.
Corrosion Resistance	The metallic radiopaque markers) were assessed for corrosion resistance according EN ISO 10555-1: 1995 + AM1:1999 + AM2:2004. The devices are exposed to corrosive conditions and then checked for signs of corrosion.	No signs of corrosion were visible on the samples tested.
Compatibility with Contrast media	Devices were stored for 1 hour in contrast medium (ionic and non-ionic), dilated to RBP and then visually inspected.	No visible damage or deformation after 1-hour in contrast solution. Balloon inflation to RBP was possible after contrast exposure.
Mechanical Testing		
Balloon Compliance Radial	The balloon is inflated incrementally and at each increment the balloon diameter is measured. Radial compliance is calculated as the difference between balloon diameter at NP and at RBP.	All balloon diameters are within tolerance and radial compliance meets acceptance criteria.
Balloon Compliance Axial	The balloon length at NP is measured with a ruler, pressure is increased up to RBP and balloon length is measured again and compared to the measured NP length to determine axial compliance.	The difference between balloon length at RBP and NP is within specification.
Balloon RBP	The balloon is inflated incrementally until burst and pressure at burst is recorded and then the balloon catheter is inspected for signs of damage and the burst failure mode is recorded.	Balloons met acceptance criteria for lower 99.9% quantile at 95% confidence interval for all sizes.
Balloon Rated Fatigue Testing	The balloons were inflated incrementally until they reached RBP, held at RBP for 30 seconds, then deflated. This was repeated 20 times. Any loss of pressure, whether due to failure of the balloon, shaft, or proximal or distal seals, was reported as a test failure. All failure modes were recorded.	Results demonstrate that 90% of the balloons will survive the test with at least 95% confidence.
Tensile Strength of the Entire Catheter	Following simulated use, a tensile strain at a unit strain rate of 20mm/min per mm length (as per ISO-10555-1) is applied along the relevant catheter region until the first sign of fracture. The force (Fmax) at first sign of damage is recorded.	Tensile strength performance (Fmax) for distal and proximal balloon sections met performance specifications.
Tip pull test	Following simulated use, a tensile strain at a unit strain rate of 20mm/min per mm length (as per ISO-10555-1) is applied along the relevant catheter region until the first sign of fracture. The force (Fmax) at first sign of damage is recorded.	All tested samples met acceptance criteria for mean tensile strength.

Test Name	Test Conditions / Specifications	Summary Results
Resistance to Kink	The test is performed by placing catheter shaft in U-shape within a vise (two fixture heads) and slowly closed at a constant speed. Force-displacement diagram is measured and the kinking point is determined to be the first significant decrease in force.	Measured mean catheter kink radius was well within the acceptance criteria.
Adhesive Strength of Catheter hydrophobic Coating	After simulated use, adhesive tape segments (2-5 cm long) are tightly affixed to the outer shaft and the balloon of the test sample. Tape is then pulled off rapidly at an angle of 80° (or 120°) and then visually checked with reflected light microscopy at a 20x magnification.	No delamination or residual particles were observed on the tape or the catheter. All samples tested passed.
Connector Test	Selected tests from ISO 594-2:1998 were performed on the Luer connector / hub: a) air tightness b) resistance to over-torqueing c) resistance to stress cracking	Connector meets acceptance criteria and complies with ISO 594-2.
Indelibility and adhesive strength of printing	The printing on the manifold of the balloon catheter inspected after being wiped for 15 seconds with an ethanol soaked fiber-free cloth.	All samples tested showed readable printing following exposure to solvent.
Post-Dilatation Test	In a simulated arterial model, balloon is positioned within a deployed stent. Balloon is inflated and held at RBP for 30s and then deflated. (Repeated 10 times.)	All samples withstood 10 inflation/deflation cycles within the stent without bursting.
Visual Inspection of packaging after exposure to adverse environmental conditions	The product shipping container was subjected to climatic stress, dropping (2x), compression, loose load vibration and vehicle vibration. Then the package was inspected for integrity and the device for damage.	All devices passed inspection of shipping container, box integrity, pouch integrity, labeling integrity, product fixation and device integrity.

Shelf life testing

The 3-year shelf life of Passeo-35 was validated by repeating the following non-clinical tests on aged samples:

- Functional testing including: dimensional verification, simulated use, inflation/deflation time, flex and kink, torque strength, catheter bond strength, tip pull, adhesive strength of catheter coating
- Pullback and reintroduction
- Balloon Compliance (radial & axial)
- Balloon Burst pressure
- Balloon fatigue

Clinical Test Data

The determination of substantial equivalency on this subject device does not rely upon the clinical data. There is no clinical data submitted in this application.

Labeling

The instructions for use and labeling were updated with relevant new device size information.

Conclusion

Based on the non-clinical performance testing using existing design controls from the predicate, the subject Passeo-35 catheter is substantially equivalent to the predicate Passeo-35 catheter.